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RE: Docket No. TMD-04-01 - **Comments on Proposed Amendments to the National List of Allowed and Prohibited Substances, 7 CFR Part 205**

**November 15, 2005**

Dear Mr. Neal:

Thank you for the opportunity to comment on the proposed amendments to the USDA National List of Allowed and Prohibited Substances (National List), Docket Number TMD-04-01. As chair of the National Organic Standards Board, I am pleased to see that this docket has been published. It is important to keep the National List process moving forward, as some of these substances were recommended by the NOSB for inclusion on the National List as long as five years ago.

I would like to share one general concern before addressing specific items. There were several materials that were recommended by the NOSB for addition to the National List as allowed synthetic substances for placement on 205.605(b). In the Federal Register Notice, dated 9/16/05, the Secretary accepts the NOSB's recommendation. However, these materials are posted with the added annotation of "made with organic \*\*\*" label ONLY.

The added annotation does not reflect the recommendations of the NOSB. As stated in OFPA 2118(d)(2), the Secretary does not have authority to add a material or exemption not recommended by the NOSB to the National List.

OFPA at Section 2118, subsection (d)(2) states:

**Sec 2118 NATIONAL LIST**

**(d) Procedure for Establishing National List**

**(2) No additions.** The Secretary may not include exemptions for the use of specific synthetic substances in the National List other than those exemptions contained in the Proposed National List or Proposed Amendments to the National List.

Further 2119 (k)(2) states:

**Sec 2119 NATIONAL ORGANIC STANDARDS BOARD**

**(k) Responsibility of the Board**

(2) **National List.** The Board shall develop the proposed National List or proposed amendments to the National List for submission to the Secretary in accordance with section 2118.

In light of recent court action in the *Harvey v. Johanns* case and subsequent changes to the OFPA made by Congress, it is inappropriate and premature for the Secretary to arbitrarily include annotations not recommended by the NOSB.

I have the following comments on specific substances.

## I. Crops

I support the comments from the Organic Material Review Institute regarding the inert ingredients used in pesticides proposed for the National List, and supply a number of additional remarks. Suggested deletions are in strikethrough mode

### 1. 205.601(m)(2) – as EPA List 3 Inerts:

- Glycerine oleate (glycerin monooleate), (CAS #s ~~111-03-5, 25496-72-4~~, 37220-82-9) for use only until December 31, 2006.
- Tetrahydrofurfuryl alcohol (CAS #97-99-4) for use only until December 31, 2006.

OMRI correctly notes that two of the forms of **glycerine oleate** have been reclassified as EPA List 4A on the August 2004 edition of the EPA's list of inert ingredients:

CAS#	Substance	EPA List#
111-03-5	9-Octadecenenoic acid (Z)-, 2,3-dihydroxypropyl ester	4A
25496-72-4	Octadecanoic acid (9Z) monoester with 1,2,3 9-propanetriol	4A
37220-82-9	glycerine oleate	3

Therefore, the references of CAS #111-03-5 and CAS #25496-72-4 are incorrect and not needed on the National List, since they now appear on EPA's List 4A. **These two CAS numbers should be removed.** The original petition for this substance for use in pesticides was for the substance with the CAS #37220-82-9. This substance should be added to the National List with the restriction that it be removed from the National List by December 31, 2006. This deadline is needed because it corresponds to EPA's process for mandated review tolerances for both active and inert ingredients under the 1996 Food Quality Protection Act.

In addition, this inert was initially petitioned in April 2003 as needed for a formulation of micronized sulfur, used to protect organic tree fruit from fungal diseases. At that time, the petitioner described a lack of other formulated sulfur products with comparable efficacy. Since that time, a number of other micronized sulfur products have become available in organic –approved forms: Micro Sulf® (NuFarm Americas, Inc.), Thiolux® Jet (Syngenta Crop Production), Micro-Sul™ (Hondo Chemical Co), CSC 80% Thiosperse (Continental Sulfur Co.).<sup>1</sup> If the EPA tolerance review does not result in a reclassification of glycerin monooleate as List 4, organic farmers still have other NOP compliant formulations available for micronized sulfur products.

In the case of **tetrahydrofurfuryl alcohol**, this inert ingredient was petitioned by a company (Amvac Chemical) for use in a pesticide in 2003. The identity of this pesticide was claimed as confidential by the petitioner, and the Technical Advisory Panel review did not provide complete information due to

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<sup>1</sup> 2005 OMRI Brand Name Product List, [http://www.omri.org/OMRI\\_datatable.htm](http://www.omri.org/OMRI_datatable.htm)

this redaction.<sup>2</sup> Alternatives could not be evaluated by the NOSB. The petitioner did state in testimony at a subsequent public NOSB meeting<sup>3</sup> that this inert is used in neem (a substance derived from a natural botanical source) products. There are many pesticides based on neem or neem derivatives available in organic NOP-compliant forms, with similar or better characteristics for efficacy.<sup>4 5</sup> Some of these were available in 2003, and more have become available since that time. The decision to permit this inert for a very limited period of time to coincide with EPA review is justified, as there are many alternatives available.

*Comment:* The redaction of confidential business information regarding petitioned substances is problematic, and hinders NOSB review. The National List petition requirements should be redrafted to provide guidance to petitioners, to advise them that while they may redact information, that lack of information may delay or impede review in this public process. Inert ingredients used in pesticides have a special status in the Organic Foods Production Act (OFPA), as they are designated as a special class of synthetics that may be approved for use in organic production.<sup>6</sup> However, it is very difficult for the NOSB to evaluate the availability of approved alternatives as required under OFPA Sec 6518(m)(6) if the active ingredient of the product is not disclosed, and this factor should be provided in notice to petitioners of inert ingredients.

**2. 205.601(h)** As slug or snail bait,  
Ferric phosphate, (CAS # 10045-86-0)

*Comment:* This substance should be added to the National List, according to NOSB review as suitable for organic production.

**3. 205.601 (n)** Seed preparations  
Hydrogen chloride (CAS # 7647-01-0) for delinting cotton seed for planting.

*Comment:* This substance should be added to the National List, according to NOSB review as suitable for organic production.

## **II. Processing Substances**

**1. 205.605(a) Nonsynthetics allowed:**  
Egg white lysozyme  
L-malic acid  
Microorganisms

*Comment:* These three substances should be added to the National List as proposed.

**2. 205.605(b) Synthetics allowed:**  
All synthetics proposed for listing under 205.065 have been given a restriction that the NOSB did **not** advise: “restricted to handling agricultural products labeled ‘made with organic ingredients.’ ” No explanation was given in the *Federal Register* for this, though it appears that the NOP sought to

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<sup>2</sup> 2003 UC Davis, Sustainable Ag Research and Education Program, THFA TAP Review p. 1, contractors note.  
<http://www.ams.usda.gov/nop/NationalList/THFATAP.pdf>

<sup>3</sup> 2003 NOSB transcript, May 14, Austin Tx. page 21. Note speaker named “Amayu” describing “Amdac” (AMVAC) products. Neem is misspelled as “lean”. Ecosin 3% is misspelled as “ecosyn”. Product “Amazin” is misspelled as “Amazon”. <http://www.ams.usda.gov/nosb/transcripts/NOSBMay2003AustinMtngTranscripts.pdf>

<sup>4</sup> 2005 B. Caldwell, Brown Rosen E., Sideman E., Shelton A., Smart C. Resource Guide for Organic Insect and Disease Management. NYSAES, Cornell Univ. p.101-111. <http://www.nysaes.cornell.edu/pp/resourceguide/index.php>

<sup>5</sup> 2005 OMRI, Ibid.

<sup>6</sup> 1990 Organic Food Production Act. Sec. 6517(c)(1)(B)(ii)

address the Court of Appeals order in *Harvey v. Johanns*. In view of the recent Congressional action to amend OFPA, this restriction should be re-evaluated. In addition, the Court order did not specifically apply to substances used as sanitizers and cleaners, and these types of substances should be considered for a separate category on the National List, regardless of the status of other synthetics.

**a. Peracetic acid / Peroxyacetic acid** – NOSB recommended this substance on Nov. 16, 2000 for direct food contact only in wash/rinse water. Allowed as sanitizer on surfaces in contact with organic food.

Recommended change to listing:

205.605(a) as sanitizer or cleaning agent:

Peracetic acid / Peroxyacetic acid (CAS #79-21-0)—for use in wash and/or rinse water according to FDA limitations. For use as a sanitizer on food contact surfaces. ~~Restricted to use in handling agricultural products labeled ‘made with organic (specified ingredients or food group(s));’ prohibited in handling agricultural products labeled “organic.”~~

*Comment:* This substance is a useful material needed for food safety purposes. It has a better environmental profile than the widely used alternative, chlorine, which has by-products known to be carcinogenic. Peracetic acid degrades rapidly, leaves little residue, and decomposes into relatively harmless naturally-occurring substances.<sup>7</sup> It is used as a disinfectant in direct contact with raw whole agricultural commodities, and the ‘MWO’ annotation is not appropriate. The substance is commonly used with hydrogen peroxide and should be annotated consistently with hydrogen peroxide. This material should be added to the National List as allowed for organic production and handling.

**b. Activated charcoal** – NOSB recommended as allowed synthetic, from vegetative sources only, for use as a filtering aid, Sept. 19, 2002

Recommended change to proposed listing:

Activated charcoal (CAS #7440-44-0; 65365-11-3)—only from vegetative sources; for use only as a filtering aid. ~~in handling agricultural products labeled ‘made with organic (specified ingredients or food group(s));’ prohibited in handling agricultural products labeled “organic.”~~

*Comment:* Activated charcoal is a processing aid that is used for filtering. The TAP review supports the annotation that in order to be used in organic processing, activated carbon must come from vegetative sources. While it may be present in incidental amounts, filtering aids—whether synthetic or non-synthetic—are required to be on the National List in order to be used in *or on* organic ingredients. There are a number of other filter aids on the List, (cellulose, bentonite, kaolite clay, and diatomaceous earth) and this addition is consistent with those.

**c. Cyclohexylamine** - NOSB recommended in Oct. 2001, for use only as a boiler water additive for packaging sterilization only.

**d. Diethylaminoethanol** - NOSB recommended in Oct. 2001, for use only as a boiler water additive for packaging sterilization only.

**e. Octadecylamine** - NOSB recommended in Oct. 2001, for use only as a boiler water additive for packaging sterilization only.

Recommended changes to proposed listing at 205.605(b):

Cyclohexylamine (CAS #108-91-8)—for use only as a boiler water additive for packaging sterilization. ~~Restricted to use in handling agricultural products labeled ‘made with organic (specified ingredients or food group(s));’ prohibited in handling agricultural products labeled “organic.”~~

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<sup>7</sup> 2000. Technical Advisory Panel Review, Peracetic Acid in processing, by OMRI for the NOSB, page 3. See [www.omri.org](http://www.omri.org)

Diethylaminoethanol (CAS #100-37-8)—for use only as a boiler water additive for packaging sterilization. ~~Restricted to use in handling agricultural products labeled ‘made with organic (specified ingredients or food group(s));’ prohibited in handling agricultural products labeled ‘organic.’~~

Octadecylamine (CAS #124-30-1)—for use only as a boiler water additive for packaging sterilization. ~~Restricted to use in handling agricultural products labeled ‘made with organic (specified ingredients or food group(s));’ prohibited in handling agricultural products labeled ‘organic.’~~

*Comment:* Cyclohexylamine, diethylaminoethanol, and octadecylamine were intended only for use in steam used to sterilize food contact surfaces, such as bottles and caps, but should be prohibited for direct contact with food. Because they are miscible in water and form azeotropes (solutions that have the same boiling point as water, and therefore cannot be separated by distillation), they become part of the food. This limited use should be reconsidered in the next sunset review period to evaluate progress made in replacing use of volatile boiler chemicals in organic food processing.

**f. Ammonium Hydroxide**

Ammonium hydroxide should **not** be added to the National List at this time. The NOSB recommendation and the proposed listing include an expiration date of October 21, 2005. The expiration date has passed, so the substance should not be added, in order to comply with the NOSB recommendation, made in October 2001. Processors have managed without use of this substance in the last four years, and there are a number of alternatives to ammonium hydroxide for boiler maintenance.<sup>8</sup> This is a volatile substance used in boiler water that carries over into organic food. It is permitted by FDA for use in milk processing, and has contact in organic milk that is subject to Ultra-High Temperature pasteurization process.

**g. Tetrasodium Pyrophosphate**

This item should be **tabled** for more public information at this time. Tetrasodium pyrophosphate (TSPP), as petitioned, becomes an ingredient in foods beyond an incidental amount. There is not complete documentation of the NOSB recommendation on TSPP available on the NOP website. The petition and TAP review are not posted. The final Board decision is not recorded, however the NOSB Handling Committee review checklist developed for the Board meeting of April 2004 is posted and the committee documented its response to the criterion regarding function of the substance. The posted checklist provides the following information:

**Question:** “Is the primary use to improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]”

**Committee Response:** “TAP – TSPP – reviewer comment; page 5; Phosphates stabilize proteins during processing so the (sic) improve finished product texture. Petition: page 4; Intended use as stated in the proposed annotation and specific uses in this petition are primarily not as a preservative, or to recreate flavor, color or texture. Its use as a dough conditioner and pH agent is indispensable because it greatly improves protein process flow... Yes, the TAP does indicate that its use is for texture but it does not state to recreate texture.”

*Comment:* The petitioner testified in April 2004 that this substance is used to condition the dough so that it can be extruded mechanically in a proprietary process to produce texturized vegetable protein, confirming that this additive is used solely for the ease of manufacturing to provide texture in order to create a meat-like consistency from a grain product.

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<sup>8</sup> 2001. OMRI. Steam Generation in Organic Food Processing Systems.  
[http://www.omri.org/AdvisoryCouncil/boiler\\_background.pdf](http://www.omri.org/AdvisoryCouncil/boiler_background.pdf)

In April 2004 the NOSB adopted criteria to determine whether a substance is “consistent with organic farming and handling” (OFPA 6518(m)(7)). Those criteria do not appear to have applied during the review of TSPP. As a processing aid that is exempt from labeling in the final product under FDA regulations, the inclusion of TSPP in organic products without clear consumer identification presents additional concerns, as consumers will not know this synthetic is in fact in the product, used to create texture.

TSPP is not approved by any other international organic standard, a fact that could lead to international trade restrictions. Further, allowance of this form of phosphate may provide justification for the many hundreds of other forms of phosphate food additives. The current National List has a narrow allowance for basic calcium phosphates used in leavening, and one use of sodium phosphate in dairy products. Potassium phosphate is only allowed for “made with organic” products.

The annotation for “use only in textured analog meat products” is vague. This expression is not a well-defined food term. The absence of an NOP or FDA definition leaves its applicability unclear. It could be interpreted to mean that TSPP can be used in any grain-based product that makes an artificial meat claim.

#### **h. Sodium Acid Pyrophosphate**

Sodium acid pyrophosphate (SAPP) was reviewed during the May 2003 NOSB meeting. The NOP Petitioned Substances website currently states “NOP returned this recommendation to the NOSB for further documentation. No further action will be taken until the requested documentation is received. The reader is reminded that use of this material is prohibited.”

*Comment:* A serious problem exists regarding documentation of the NOSB’s recommendation on SAPP. The NOSB meeting transcript describes a supplemental TAP review conducted for sodium acid pyrophosphate petition that did not address the processing criteria, and did not address the issue of international recognition of this substance.<sup>9</sup> The supplemental review has never been made available to the public. There is no documentation of the decision using the checklist developed for all criteria. Addition of SAPP to the National List should be **tabled** until supporting information for SAPP can be opened to a fair public review. All information supporting the SAPP recommendation should be publicly available for comment prior to final rulemaking on this substance.

### **III. Other substances Not Included**

There are a number of outstanding NOSB recommendations that have not been included in the docket. It would be helpful to have a statement from NOP regarding the status of these items. Numerous livestock materials and two non-organic agricultural ingredients have been recommended by the NOSB, as shown below:

#### **205.603- Synthetic substances allowed in organic livestock production**

Activated carbon  
Adrenaline  
Atropine  
Bismuth subsalicylate  
Butorphanol  
Calcium borogluconate  
Calcium propionate

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<sup>9</sup> 2003. NOSB Meeting Transcript, May 13, pp 307-310.  
<http://www.ams.usda.gov/nosb/transcripts/NOSBMay132003AustinMtng.pdf>

Epinephrine  
Excipients for livestock medications  
Flunixin  
Furosemide  
Kaolin Pectin  
Magnesium oxide  
Magnesium hydroxide  
Moxidectin  
Peracetic acid  
Pheromones  
Poloxalene  
Potassium sorbate  
Propylene glycol  
Tolazoline  
Xylazine

**205.606** Nonorganically produced agricultural products .....for use in processed products

Gelatin  
Shellac, Orange—unbleached

*Comment:* Resolution is needed regarding the livestock substances in order for organic livestock producers and veterinarians to provide comprehensive and humane animal health care.

Gelatin and shellac both had complete TAP reviews, and the NOSB voted to list them in 205.606 on May 07, 2002. These should be added promptly to 205.606, as we now have clarification that all non-organic agricultural substances must appear on the National List in order to be used in products labeled “organic.”

## **Conclusion**

Once again, I appreciate the opportunity to comment on the proposed amendments to the USDA National List of Allowed and Prohibited Substances (National List), Docket Number TMD-04-01. It is important to keep the National List process moving forward, consistent with NOSB recommendations.

Respectfully submitted,

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